REMARKS

Reconsideration of the instant application in view of the above amendments and the following remarks is respectfully requested. As of the mailing date of the Office Action dated August 6, 2007, claims 1, 3, 4, 11 and 15 were pending and under examination. By the present amendment, claim 1 is amended to more specifically recite certain aspects of the invention. Support for these amendments may be found throughout the specification and claims as originally filed. Therefore, the amendments do not constitute new matter. The above amendments are not to be construed as acquiescence with regard to the Examiner's rejections and are made without prejudice to prosecution of any subject matter removed or modified by this amendment in a related divisional, continuation or continuation-in-part application. Following the present amendments, claims 1, 3, 4, 11 and 15 are pending and under consideration.

Applicants wish to thank the Examiner for the productive telephone interview of October 17, 2007 during which the outstanding rejections were discussed as well as interpretation of the claim language.

Claim Rejections Under 35 U.S.C. § 101 (Utility) and 35 U.S.C. § 112, first paragraph (enablement)

Claims 1, 3, 4, 11 and 15 stand rejected under 35 U.S.C. § 101 because the claimed invention allegedly lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility. The claims are also rejected under 35 U.S.C. § 112, first paragraph as allegedly lacking enablement since one of skill in the art would not know how to make and use the claimed invention due to its alleged lack of utility. In particular, in response to Applicants' amendment filed May 16, 2007, the Action asserts that by detecting the sequence of SEQ ID NO:52 in normal breast tissue, one would not be able to distinguish between a normal and cancerous breast tissue. The Action goes on to reiterate that the presence of a polynucleotide in a tissue derived from cancer is not sufficient for establishing utility absent some information regarding a correlative or causal relationship between the expression of the claimed cDNA and the disease and additionally states that there

must be some expression pattern that would allow the claimed polynucleotide to be used in a diagnostic manner (*i.e.*, overexpression in diseased tissue compared to normal tissue).

Applicants respectfully traverse this rejection and submit that the claimed sequence of SEQ ID NO:52 was identified from a breast tumor cDNA library. However, contrary to the Action's assertion, and as noted in Applicants' response filed May 16, 2007, mRNA expression analysis was performed for this sequence and is clearly described in the specification as filed at page 101, lines 10-29. In particular, the specification states that "...mRNA expression levels in breast tumor, normal breast and various other normal tissues were determined using microarray technology." Further, the specification states "The determined cDNA sequences of 131 clones determined to be over-expressed in breast tumor tissue compared to other tissues tested by a visual analysis of the microarray data are provided in SEQ ID NO:1-25 and 42-137."

Additionally, the specification notes throughout that over-expression is generally at least two fold greater in tumor tissues as compared to normal tissue. For example, the specification clearly discloses at page 48, lines 7-11:

> For example, a polynucleotide may be identified, as described in more detail below, by screening a microarray of cDNAs for tumor-associated expression (*i.e.,* expression that is at least two fold greater in a tumor than in normal tissue, as determined using a representative assay provided herein).

Therefore, Applicants submit that the skilled artisan would readily recognize in view of the teachings in the specification as filed that the polynucleotide set forth in SEQ ID NO:52 is indeed overexpressed in breast tissue as compared to other normal tissues and could be used, for example, in any number of diagnostic settings. Contrary to the Action's assertion, detection of SEQ ID NO:52 in normal breast tissue does not mean that using "a probe" based on SEQ ID NO:52 would not distinguish between normal and cancerous breast tissue. As would be readily recognized by the skilled artisan, for those instances where expression is tissue-specific (*e.g.*, breast-specific expression as opposed to breast-tumor specific expression) such as in the case of the B854P antigen encoded by the polynucleotide that comprises the sequence of SEQ ID

NO:52 (*i.e.*, the polynucleotide of SEQ ID NO:305), the breast tissue-specific expression pattern can be exploited, for example, in the setting of metastatic breast cancer cells that can be detected in the blood.

As further confirmed by the enclosed Declaration of Dr. Davin Dillon, originally filed in related Application No. 10/010,742 (now abandoned), real time PCR analysis showed that the polynucleotide set forth in SEQ ID NO:305 (which comprises SEQ ID NO:52) is overexpressed in breast tumor tissue but is not expressed in a panel of other normal tissues. Additionally, as evidenced by the enclosed Declaration, and as would be reasonably expected by the skilled artisan, the protein encoded by the polynucleotide set forth in SEQ ID NO:305 is expressed in breast tumors and normal breast tissue but not in a variety of other normal tissues as shown by immunohistochemical analysis.

Similar to the well-known breast antigen, mammaglobin, because the B854P sequence is expressed in breast tissue, but is not found in the majority of other normal tissues (in particular, normal resting and activated PBMC; see Figure 2 of enclosed Declaration), one specific utility is the identification of breast-derived cells in secondary locations. For example, in patients diagnosed with breast cancer, identification of breast-derived cells in blood would indicate metastasis, a key piece of information for proper treatment regimen. In such a scenario, expression in other tissues, such as colon, would not bar utility of identification of breast-derived cells since the patient is already diagnosed as having breast cancer and it would be highly unlikely that the cells would be colon-derived. This type of utility has been confirmed by the skilled artisan as evidenced by the enclosed Declaration of Dr. Dillon.

Accordingly, Applicants submit that they have shown that the polynucleotide set forth in SEQ ID NO:52 is expressed in breast tissues and therefore, the skilled artisan would readily recognize any number of utilities for the claimed invention, including, for example, as a diagnostic tool for breast cancer. Reconsideration of the claims and withdrawal of the rejection are respectfully requested.

Claim Rejections Under 35 U.S.C. § 112, first paragraph (written description)

Claims 1, 3, 4, 11 and 15 stand rejected under 35 U.S.C. § 112 because the claimed invention allegedly lacks written description. In particular, the Action has interpreted the claim language "sequence provided in SEQ ID NO:52" as "sequence comprising SEQ ID NO:52". As such, the Action asserts that the specification as filed does not adequately describe a representative number of fragment sequences and that there is no description of common attributes or features of the members of the genus of sequences "comprising" fragments of SEQ ID NO:52 as allegedly claimed.

Applicants respectfully traverse the rejection and note that the claims as amended in Applicants' amendment filed May 16, 2007 read "An isolated polynucleotide consisting of the sequence provided in SEQ ID NO: 52, the complement thereof, or a fragment thereof wherein the fragment consists of at least 20 contiguous residues of the sequence provided in SEQ ID NO:52, or the complement thereof, and wherein the fragment detects the presence of the sequence provided in SEQ ID NO:52, or the complement thereof, in a biological sample." Furthermore, in Applicants' amendment filed May 16, 2007, in reference to the § 102 rejection, Applicants stated "Applicants submit that none of the cited references teaches or suggests a sequence that consists of the exact sequence of SEQ ID NO:52…." Accordingly, it is unclear how this claim language can be interpreted to mean anything other than a sequence consisting of the sequence of SEQ ID NO:52.

Nevertheless, without acquiescing to the rejection and as discussed with the Examiner during the telephone interview on October 17, 2007, Applicants have amended claim 1 for clarification to recite "An isolated polynucleotide consisting of SEQ ID NO:52, the complement thereof, or a fragment thereof wherein the sequence of the fragment consists of at least 20 contiguous residues of SEQ ID NO:52, or the complement thereof, and wherein the fragment detects the presence of the sequence provided in SEQ ID NO:52, or the complement thereof, in a biological sample." Further to the discussion during the above-mentioned telephone interview, Applicants submit that this amendment obviates the rejection. Reconsideration of the claims and withdrawal of the rejection are respectfully requested.

Claim Rejections Under 35 U.S.C. § 102

Claim 1 stands rejected under 35 U.S.C. § 102(b) as allegedly anticipated by GenBank accession number AA193540. Claims 1, 3, 4 and 11 stand rejected under 35 U.S.C. § 102(e) as allegedly anticipated by Yang et al (WO 01/51638). As discussed during the interview of October 17, 2007, Applicants understand that the rejection is based on the interpretation of the claims as "sequence comprising SEQ ID NO:52".

Without acquiescing to the rejection and without prejudice, as noted above, Applicants have amended the claims solely for the purposes of clarity to recite "An isolated polynucleotide consisting of SEQ ID NO:52, the complement thereof, or a fragment thereof wherein the sequence of the fragment consists of at least 20 contiguous residues of SEQ ID NO:52, or the complement thereof, and wherein the fragment detects the presence of the sequence provided in SEQ ID NO:52, or the complement thereof, in a biological sample." Applicants submit that none of the cited references teach or suggest a sequence that consists of the exact sequence of SEQ ID NO:52 or a fragment thereof that consists of at least 20 contiguous nucleotides thereof. As such, Applicants submit that the claimed invention is not anticipated by the cited references. Reconsideration of the claims and withdrawal of the rejection are respectfully requested.

Claim Rejections Under 35 U.S.C. § 103

Claim 15 stands rejected under 35 U.S.C. § 103 as allegedly unpatentable over Yang *et al.* (WO 01/51638) and the Stratagene Catalog (page 39, 1988). In particular, the Action asserts that Yang *et al.* teach oligonucleotides which hybridize to SEQ ID NO:35 (the complement of which is 100% identical, over nucleotides 314-692, to SEQ ID NO:52) but do not teach kits. The Action relies on the Stratagene Catalog to make up this deficiency. As discussed during the interview of October 17, 2007, Applicants understand that the rejection is based on the interpretation of the claims as "sequence comprising SEQ ID NO:52".

Without acquiescing to the rejection and without prejudice, as noted above, Applicants have amended the claims solely for the purposes of clarity to recite "An isolated polynucleotide consisting of SEQ ID NO:52, the complement thereof, or a fragment thereof

wherein the sequence of the fragment consists of at least 20 contiguous residues of SEQ ID NO:52, or the complement thereof, and wherein the fragment detects the presence of the sequence provided in SEQ ID NO:52, or the complement thereof, in a biological sample." Applicants submit that the cited references, taken for what they teach individually or as a whole, do not teach or suggest the claimed invention. In particular, as noted above, Yang *et al.* does not teach or suggest a sequence that consists of the sequence of SEQ ID NO:52 or a fragment thereof that consists of at least 20 contiguous nucleotides of SEQ ID NO:52. Page 39 of the Stratagene Catalog does not overcome this deficiency and, in fact, teaches no sequences at all. As such, Applicants submit that the claimed invention is not obvious in view of the cited references. Reconsideration of the claims and withdrawal of the rejection are respectfully requested.

Rejections under nonstatutory obviousness-type double patenting

Claims 1, 3, 4 and 11 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 1, 3, 4, 22 and 23 in copending Application No. 10/010,742.

Applicants submit that copending Application No. 10/010,742 has been abandoned, thereby obviating the rejection.

In view of the above amendments and remarks, the claims are now believed to be in condition for allowance. However, should any further issue require attention prior to allowance, the Examiner is requested to contact the undersigned at 206-622-4900 to resolve same.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Respectfully submitted,

SEED Intellectual Property Law Group PLLC

/Julie A. Urvater/
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JAU:ms

Enclosure:
Copy of Declaration of Davin Dillon originally filed in related Application No. 10/010,742

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